

Medical Policy Manual

Topic: Cooling Devices Used in the Home Setting

Date of Origin: January 1996

Section: DME

Last Reviewed Date: May 2014

Policy No: 7

Effective Date: August 1, 2014

IMPORTANT REMINDER

Medical Policies are developed to provide guidance for members and providers regarding coverage in accordance with contract terms. Benefit determinations are based in all cases on the applicable contract language. To the extent there may be any conflict between the Medical Policy and contract language, the contract language takes precedence.

PLEASE NOTE: Contracts exclude from coverage, among other things, services or procedures that are considered investigational or cosmetic. Providers may bill members for services or procedures that are considered investigational or cosmetic. Providers are encouraged to inform members before rendering such services that the members are likely to be financially responsible for the cost of these services.

DESCRIPTION

Cooling devices use chilled water to decrease the local temperature of tissue. There are a variety of cooling devices available, ranging from gravity-fed devices that are manually filled with iced water, to motorized units that both cool and circulate the chilled water. These devices are typically used when ice packs would normally be applied, e.g., after orthopedic surgical procedures.

Cold and/or compression therapy following surgery or musculoskeletal and soft tissue injury has long been accepted in the medical field as an effective tool for reducing inflammation, pain, and swelling. Ice packs and various bandages and wraps are commonly used. In addition, a variety of continuous cooling devices are commercially available and can be broadly subdivided into those providing passive cold therapy, and those providing active cold therapy using a mechanical device.

Passive Cold Therapy

The CryoCuff® device and the Polar Care Cub devices are examples of passive cooling devices. The CryoCuff® device consists of an insulated container filled with cold water that is attached to a compressive cuff. When the container is raised, the water fills and pressurizes the cuff. The amount of pressure is proportional to the height of the container. When body heat warms the water, the cooler is lowered and the water drains out. The cooler is then raised above the affected limb and cold water refills the compressive cuff. The PolarCare Cub unit consists of pads held in place with elastic straps,

which may also provide compression. The pads are attached to a built-in hand pump which circulates the water through the pads at the same time as increasing the compression around the joint.

Active Cold Therapy

In active devices, a motorized pump both circulates cold water and may also provide pneumatic compression. For example, the AutoChill® device, which may be used in conjunction with a CryoCuff®, consists of a pump that automatically exchanges water from the cuff to the cooler, eliminating the need for manual water recycling. The Hot/Ice Thermal Blanket is another example of an active cooling device, which consists of two rubber pads connected by a rubber hose to the main cooling unit. Fluid is then circulated via the hose through the thermal blankets. The temperature of the fluid is controlled by the main unit and can be either hot or cold. The Game Ready™ Accelerated Recovery System is an example of an active cooling device combined with a pneumatic compression component. The system consists of various soft wraps and a computer-controlled unit to circulate the water through the wraps. The ProThermo and the NanoTherm™ Therapy Unit (ThermoTek), OPTI-ICE™ Cold Therapy System, Hilotherm® Clinic facial mask (Hilotherapy), ThermaZone® and the Iceman® Cold Therapy (DonJoy) are other examples of combination active cooling with and without compression devices.

MEDICAL POLICY CRITERIA

Active and passive cooling devices, with or without compression, used in the home setting are considered **not medically necessary**.

SCIENTIFIC EVIDENCE

The primary difference between ice packs and passive cooling devices is that water recirculation is more convenient with passive cooling devices. Active cooling devices are designed to provide a steady low temperature, which, in addition to convenience, might provide a unique benefit compared to the more variable temperature achieved with ice packs or passive cooling devices. Benefit is typically focused on pain control and swelling.

To demonstrate a benefit beyond convenience, the following features must be included in the clinical trial design:

- Pain is a subjective outcome and, thus, may be susceptible to placebo effects. Therefore, randomized controlled trials (RCTs) are required to control for the placebo effect and determine its magnitude.
- The appropriate control group for RCTs of cooling devices is one in which ice packs are used since this is considered the standard delivery method for cold therapy.
- For passive devices, the number of exchanges of ice bags and episodes of water recirculation must be the same.
- For devices that deliver combined cold and compression therapy, the control group should received both ice packs and compression wraps.

Literature Appraisal

The focus of this literature appraisal is on randomized trials of cold therapy in the home setting that

included the relevant control group of standard ice packs. RCTs performed in the inpatient setting^[1] and those that failed to include the appropriate control group^[2-8] were excluded from this review.

Passive Cooling Devices

Randomized Controlled Trials

- Whitelaw and colleagues reported on the results of a trial that randomized 102 patients undergoing knee arthroscopy in the outpatient setting to receive either the CryoCuff® device or traditional ice therapy.^[9] The number of exchanges of ice packs and water recirculation was not reported. There was no significant difference in average pain assessment, although those in the CryoCuff® group reported decreased pain medication use compared to the control group.
- Healy and colleagues reported that the CryoCuff® device provided no benefit for pain control or swelling compared to ice packs in a randomized trial of 76 patients (105 knees) undergoing total knee arthroplasty.^[10] No data was provided on the number of ice pack exchanges, although the water was recirculated in the CryoCuff® device every one to four hours. The duration of therapy and whether it was applied in the inpatient or outpatient setting is not clear from the published article.
- In a randomized trial comparing CryoCuff (n=25) to ice packs (n=26) following arthroscopic wrist surgery, Meyer-Marcotty et al. reported no significant between-group differences in swelling, range of motion, use of pain medication, and subjective functional impairment.^[11] Pain levels were significantly less in the CryoCuff group for postoperative day 1 and 2, but not significantly different from the control group during the remainder of the 21 days follow-up.

Manually Operated Passive Cooling Devices

Intermittent Cooling Regimens

Konrath and colleagues reported on the results of a trial that randomized 103 patients undergoing ACL reconstruction to one of four different postoperative cold therapy strategies.^[12]

1. Active cooling with a Polar Care pad set at a temperature of 40 to 50 degrees Fahrenheit
2. Active cooling with a Polar Care pad set at a temperature of 70 to 80 degrees Fahrenheit
3. Ice packs
4. No cold therapy

Both the water in the Polar Care pad and the ice packs were changed every 4 hours. The length of hospital stay, range of motion at discharge, use of oral and intramuscular pain medicine and drain output were not significantly different between groups. These results suggest that the Polar Care device provided no incremental benefit in comparison with ice packs when used with the same intermittent treatment regimen.

Continuous Versus Intermittent Cooling Regimens

- Hochberg randomized 72 patients to either continuous cryotherapy using a temperature-controlled cooling blanket to intermittent 20-minute ice applications over the first 3 days after carpal tunnel release.^[13] Pain and wrist circumference were measured preoperatively, immediately after surgery, and on postoperative day 3. Continuous cooling resulted in significantly reduced pain and wrist circumference on postoperative day 3 in comparison to intermittent ice packs. Larger RCTs are needed to validate these outcomes.

- Schroder and Passler compared the CryoCuff device to ice therapy in 44 patients who had undergone ACL repair.^[14] Those randomly receiving ice therapy received an ice bag 3 times a day postoperatively. While those randomly assigned to the CryoCuff group reported significant decreases in pain, swelling, and analgesic use, it is not clear whether icing 3 times a day is a typical icing regimen.

Active Cooling Devices

- In a 2008 randomized controlled trial (n=60), Woolf et al. compared a temperature-controlled cryotherapy device to a standard icing regimen following outpatient knee arthroscopy.^[15] Seven patients (12%) were excluded from analysis or lost to follow-up. Both groups were instructed to apply the treatment for 20 minutes every 2 hours during waking hours for the first 4 days after surgery. For the night time, the cooling device group was instructed to use the device throughout the first 4 nights, whereas the control group was advised to use ice packs at their own discretion. No differences in daytime pain were observed between the two groups. There was a tendency for more patients in the cryotherapy group to report that they did not awaken from pain during the night; this difference reached significance only for postoperative day 2 (36% vs. 6%, p = 0.04). Additional study with a larger number of patients is needed to determine whether use of continuous cooling at night improves health outcomes.
- Several studies have been reported by a single research group comparing the Hilotherm® device versus cooling compresses. In a randomized observer-blinded study by Modabber et al., 42 patients were treated with open reduction and internal fixation for zygomatic bone fractures and then randomly assigned to a Hilotherm® cooling face mask or a standard cooling compress.^[16] Both cooling methods were intended to be used continuously for 12 hours daily for 3 days after surgery; however, no data were provided on whether patients in the control group used the cold compresses for a similar amount of time as patients in the treatment group who used the face mask. Blinded evaluation with a 3-dimensional optical scanner showed a significant reduction in swelling on day 1, 2, 3, and 7 for the Hilotherm® group; however, no difference in swelling was observed between the groups on postoperative day 28. The visual analog scale (VAS) for pain was lower in the Hilotherm® group on day 1 (2.38 vs. 4.10 on a 10-point scale, p=0.00105) and day 2 (2.34 vs. 4.38, p=0.00003), but not on day 7 (1.43 vs. 1.90, p=0.11627). There were also significant differences between the groups for postoperative neurologic score and eye motility and diplopia on postoperative day 1.
- Another randomized study with 32 patients assessed postoperative swelling of bilateral mandibular fractures using the Hilotherm® cooling mask around the head and jaw.^[17] The study design was similar to that reported by Modabber et al. Swelling was reduced for the cooling mask group on day 1, 2, and 3 after surgery. VAS for pain was also reduced for the cooling mask group on day 1 (3.87 vs 5.53) and day 2 (3.63 vs 6.31). There was no significant difference between groups in postoperative neurologic score, trismus, or mandibular dysfunction. In addition, it is not clear that the cold compresses used by the control group were applied in a similar frequency as the masks used in the treatment group, limiting conclusions regarding the superiority of the Hilotherm cooling mask compared to standard postoperative therapy regimens.

Combination Active Cooling and Compression (Cryopneumatic) Devices

- A multicenter randomized trial with 280 total knee arthroplasty (TKA) patients compared the GameReady cryopneumatic device versus ice packs with static compression.^[18] On discharge from the hospital, the treatments were given at the same application cycle of 1 hour on and 30 minutes off.

Compliance rates were similar for the 2 groups. Blinded evaluation of 187 patients (67% of patients had complete evaluations) found no significant difference between the groups in VAS for pain, range of motion, 6-minute walk test, timed up and go test, or knee girth under this more typical icing regimen. Narcotic consumption was decreased from 680 mg to 509 mg morphine equivalents over the first 2 weeks (14 mg less per day), and patient satisfaction was increased with the cryopneumatic device.

- Waterman et al. reported a randomized controlled trial (RCT) of the GameReady device in 36 patients with ACL reconstruction.^[19] Patients were instructed to use ice or the cryopneumatic device for 30 minutes at least 3 times per day and return to the clinic at 1,2, and 6 weeks postoperatively. Compliance during the first 2 weeks was not significantly different between the 2 groups (100% for GameReady and 83% for icing). The primary outcome measure (VAS) was not comparable at baseline, limiting interpretation of the results. There were no significant differences between the groups for knee circumference, the Lysholm short form-36, SF-36, or single assessment numerical evaluation (SANE) scores. A greater percentage of patients treated with the GameReady device discontinued narcotic use by 6 weeks (83% vs 28%).

Other Devices and Indications

A literature search did not identify any published articles focusing on the role of cooling devices in nonsurgical settings or for nonsurgical indications, e.g., treatment of sprains or strains, or chiropractic treatments.

Clinical Practice Guidelines

No clinical practice guidelines from U.S. professional associations were found that recommend use of active or passive cooling devices or combination cold/compression devices.

Summary

To understand whether cooling devices provide any added health benefits over conventional ice packs, comparisons in well-designed randomized controlled trials are needed. The majority of the published randomized studies of cooling devices failed to adequately describe the cooling regimens and/or include a relevant control group using standard ice pack treatment. When cooling devices and ice packs were used with the same regimen, no differences in health outcomes were observed. Currently available evidence is insufficient to determine whether cooling with active or passive devices, with or without compression, results in improved health outcomes or provides a benefit beyond convenience when compared to usual ice pack exchange in the home environment. Therefore, use of these cooling devices for any indication is considered not medically necessary.

REFERENCES

1. Adie, S, Naylor, JM, Harris, IA. Cryotherapy after total knee arthroplasty a systematic review and meta-analysis of randomized controlled trials. *J Arthroplasty*. 2010 Aug;25(5):709-15. PMID: 19729279
2. Brandsson, S, Rydgren, B, Hedner, T, et al. Postoperative analgesic effects of an external cooling system and intra-articular bupivacaine/morphine after arthroscopic cruciate ligament surgery. *Knee Surg Sports Traumatol Arthrosc*. 1996;4(4):200-5. PMID: 9046503

3. Levy, AS, Marmar, E. The role of cold compression dressings in the postoperative treatment of total knee arthroplasty. *Clin Orthop Relat Res.* 1993 Dec(297):174-8. PMID: 7902225
4. Cohn, BT, Draeger, RI, Jackson, DW. The effects of cold therapy in the postoperative management of pain in patients undergoing anterior cruciate ligament reconstruction. *Am J Sports Med.* 1989 May-Jun;17(3):344-9. PMID: 2729484
5. Barber, FA, McGuire, DA, Click, S. Continuous-flow cold therapy for outpatient anterior cruciate ligament reconstruction. *Arthroscopy.* 1998 Mar;14(2):130-5. PMID: 9531122
6. Dervin, GF, Taylor, DE, Keene, GC. Effects of cold and compression dressings on early postoperative outcomes for the arthroscopic anterior cruciate ligament reconstruction patient. *J Orthop Sports Phys Ther.* 1998 Jun;27(6):403-6. PMID: 9617725
7. Edwards, DJ, Rimmer, M, Keene, GC. The use of cold therapy in the postoperative management of patients undergoing arthroscopic anterior cruciate ligament reconstruction. *Am J Sports Med.* 1996 Mar-Apr;24(2):193-5. PMID: 8775119
8. Saito, N, Horiuchi, H, Kobayashi, S, Nawata, M, Takaoka, K. Continuous local cooling for pain relief following total hip arthroplasty. *J Arthroplasty.* 2004 Apr;19(3):334-7. PMID: 15067647
9. Whitelaw, GP, DeMuth, KA, Demos, HA, Schepsis, A, Jacques, E. The use of the Cryo/Cuff versus ice and elastic wrap in the postoperative care of knee arthroscopy patients. *Am J Knee Surg.* 1995 Winter;8(1):28-30; discussion -1. PMID: 7866800
10. Healy, WL, Seidman, J, Pfeifer, BA, Brown, DG. Cold compressive dressing after total knee arthroplasty. *Clin Orthop Relat Res.* 1994 Feb(299):143-6. PMID: 7907012
11. Meyer-Marcotty, M, Jungling, O, Vaske, B, Vogt, PM, Knobloch, K. Standardized combined cryotherapy and compression using Cryo/Cuff after wrist arthroscopy. *Knee Surg Sports Traumatol Arthrosc.* 2011 Feb;19(2):314-9. PMID: 20927506
12. Konrath, GA, Lock, T, Goitz, HT, Scheidler, J. The use of cold therapy after anterior cruciate ligament reconstruction. A prospective, randomized study and literature review. *Am J Sports Med.* 1996 Sep-Oct;24(5):629-33. PMID: 8883683
13. Hochberg, J. A randomized prospective study to assess the efficacy of two cold-therapy treatments following carpal tunnel release. *J Hand Ther.* 2001 Jul-Sep;14(3):208-15. PMID: 11511016
14. Schroder, D, Passler, HH. Combination of cold and compression after knee surgery. A prospective randomized study. *Knee Surg Sports Traumatol Arthrosc.* 1994;2(3):158-65. PMID: 7584198
15. Woolf, SK, Barfield, WR, Merrill, KD, McBryde, AM, Jr. Comparison of a continuous temperature-controlled cryotherapy device to a simple icing regimen following outpatient knee arthroscopy. *J Knee Surg.* 2008 Jan;21(1):15-9. PMID: 18300666
16. Modabber, A, Rana, M, Ghassemi, A, Gerressen, M, Gellrich, NC, Holzle, F. Three-dimensional evaluation of postoperative swelling in treatment of zygomatic bone fractures using two different cooling therapy methods: a randomized, observer-blind, prospective study. *Trials.* 2013;14:238. PMID: 23895539
17. Rana, M, Gellrich, NC, von See, C, et al. 3D evaluation of postoperative swelling in treatment of bilateral mandibular fractures using 2 different cooling therapy methods: a randomized observer blind prospective study. *Journal of cranio-maxillo-facial surgery : official publication of the European Association for Cranio-Maxillo-Facial Surgery.* 2013 Jan;41(1):e17-23. PMID: 22626630
18. Su, EP, Perna, M, Boettner, F, et al. A prospective, multi-center, randomised trial to evaluate the efficacy of a cryopneumatic device on total knee arthroplasty recovery. *J Bone Joint Surg Br.* 2012 Nov;94(11 Suppl A):153-6. PMID: 23118406

19. Waterman, B, Walker, JJ, Swaims, C, et al. The efficacy of combined cryotherapy and compression compared with cryotherapy alone following anterior cruciate ligament reconstruction. *J Knee Surg.* 2012 May;25(2):155-60. PMID: 22928433
20. BlueCross BlueShield Association Medical Policy Reference Manual "Cooling Devices Used in the Outpatient Setting." Policy No. 1.01.26

CROSS REFERENCES

None

CODES	NUMBER	DESCRIPTION
CPT	None	
HCPCS	E0218	Water circulating cold pad with pump
	E0236	Pump for water circulating pad